

Message Text

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ORIGIN EB-07

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FDA:RSHELTON

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FM SECSTATE WASHDC

TO ALL DIPLOMATIC AND CONSULAR POSTS

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INFORM CONSULS

E.O. 11652: N/A

TAGS: ETRD, TBIO

SUBJECT: U.S. BANS USE OF RED DYE NO. 2

1. AFTER TWO TEMPORARY FEDERAL COURT DELAYS, FDA ON FEBRUARY 10 PUBLISHED IN FEDERAL REGISTER REGULATIONS TERMINATING THE PROVISIONAL LISTING AND CERTIFICATION OF THE COLOR ADDITIVE FD&C RED NO. 2. THE FDA DETERMINED THAT SUCH ACTION IS NECESSARY TO PROTECT PUBLIC HEALTH. AFTER FEBRUARY 12, 1976, ADDING FD&C RED NO. 2 TO ANY FOOD, DRUG OR COSMETIC WILL CAUSE SUCH PRODUCT TO BE ADULTERATED WITHIN THE MEANING OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT. ANY PRODUCT CONTAINING RED DYE NO. 2 WHICH WAS PACKED BEFORE AND INCLUDING FEBRUARY 12 WILL ENJOY FREE SALE. ANY PRODUCT PACKED AFTER THAT DATE WHICH CONTAINS THE DYE SHOULD NOT BE INTRODUCED INTO THE COMMERCE OF THE U.S.

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2. THE FOLLOWING PORTIONS OF THE FDA NOTICE ARE PROVIDED

AS AN AID IN DEALING WITH QUESTIONS WHICH MAY ARISE AT
POSTS: QUOTE...

.... THE COMMISSIONER CONCLUDES THAT THE PROVISIONAL
LISTING OF FD&C RED NO. 2 SHOULD BE TERMINATED BECAUSE SUCH
ACTION IS NECESSARY TO PROTECT THE PUBLIC HEALTH, IN THAT
QUESTIONS HAVE BEEN RAISED ABOUT THE SAFETY OF THE COLOR

ADDITIVE AND THE AVAILABLE DATA DO NOT PERMIT A DETER-
MINATION OF SAFETY.

QUOTE ALL CERTIFICATES HERETOFORE ISSUED FOR BATCHES OF
FD&C RED NO. 2 ARE HEREBY CANCELLED, EFFECTIVE FEBRUARY
12, 1976. AFTER FEBRUARY 12, 1976, ADDING FD&C RED NO. 2
TO ANY FOOD, DRUG, OR COSMETIC WILL CAUSE SUCH PRODUCT TO
BE ADULTERATED WITHIN THE MEANING OF THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT (21 U.S.C. 301 ET SEQ.) AND SUB-
JECT TO REGULATORY ACTION. THIS PROHIBITION APPLIES TO
THE USE OF STRAIGHT COLORS, LAKES, AND MIXTURES OF
STRAIGHT COLORS WITH INGREDIENTS FUNCTIONING ONLY AS
DILUENTS. THE COMMISSIONER CONCLUDES THAT THE PROTECTION
OF THE PUBLIC HEALTH DOES NOT REQUIRE THE RECALL FROM THE
MARKET OF FOOD, DRUGS, AND COSMETICS CONTAINING THE COLOR
ADDITIVE, OR THE DESTRUCTION OF PRODUCTS IN PREPARATION
TO WHICH THE COLOR ADDITIVE HAS ALREADY BEEN ADDED.

QUOTE THIS ACTION APPLIES TO EXTERNALLY APPLIED PRODUCTS
AS WELL AS TO THOSE INTENDED FOR INGESTION, AND TO PET
FOOD AND ANIMAL FEED AS WELL AS TO HUMAN FOOD.

QUOTE MANUFACTURERS OF NEW DRUGS AND NEW ANIMAL DRUGS
(INCLUDING CERTIFIABLE ANTIBIOTICS FOR ANIMAL USE) CON-
TAINING FD&C RED NO. 2 MAY EITHER DELETE THE COLOR ADDI-
TIVE OR SUBSTITUTE A DIFFERENT COLOR IN ACCORDANCE WITH
THE PROVISIONS OF 314.8(D)(3) AND (E) OR 514.8(D)(3) AND
(E), AS APPROPRIATE (21 CFR 314.8(D)(3) AND (E), 514.8
(D)(3) AND (E)) THE APPLICANT SHALL SUBMIT DATA PROVIDING
THE NEW COMPOSITION AND SHOWING THAT THE CHANGE IN COMPO-
SITION DOES NOT INTERFERE WITH ANY ASSAY OR OTHER CONTROL
PROCEDURES USED IN MANUFACTURING THE DRUG, OR THAT THE
ASSAY AND OTHER CONTROL PROCEDURES HAVE BEEN REVISED TO
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MAKE THEM ADEQUATE. ALSO, THE APPLICANT SHALL SUBMIT
DATA AVAILABLE TO ESTABLISH THE STABILITY OF THE REVISED
FORMULATION, OR IF THE DATA ARE TOO LIMITED TO SUPPORT A
CONCLUSION THAT THE DRUG WILL RETAIN ITS DECLARED POTENCY
FOR A REASONABLE

MARKETING PERIOD, A COMMITMENT TO TEST THE STABILITY OF
MARKETED BATCHES AT REASONABLE INTERVALS, TO SUBMIT THE

DATA AS THEY BECOME AVAILABLE, AND TO RECALL FROM THE MARKET ANY BATCH FOUND TO FALL OUTSIDE THE APPROVED SPECIFICATIONS FOR THE DRUG.

THE COMMISSIONER IS AWARE THAT SUPPLIES OF ALTERNATIVE COLOR ADDITIVES MAY BE DIFFICULT TO OBTAIN IMMEDIATELY. CONSEQUENTLY, FOOD AND DRUG LABELING STATING THAT THE PRODUCT CONTAINS QUOTE ARTIFICIAL COLOR END QUOTE BECAUSE OF THE PRIOR INCLUSION OF FD&C RED NO. 2 MAY CONTINUE TO BE USED WITH UNCOLORED PRODUCT DURING THE TIME NECESSARY TO OBTAIN SUPPLIES OF ALTERNATIVE COLOR INGREDIENTS OR UNTIL THE CURRENT SUPPLIES OF LABELING ARE USED, WHICH-EVER OCCURS FIRSTEND QUOTE.

3. ALTHOUGH THE U.S. COURT OF APPEALS HAS ALLOWED THE BAN TO GO INTO IMMEDIATE EFFECT, IT HAS SCHEDULED A FULL HEARING APRIL 15 ON AN APPEAL BY MANUFACTURERS WHO ARE ATTEMPTING TO REVERSE THE ACTION AGAINST USE OF RED DYE NO. 2. INGERSOLL

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Margaret P. Grafeld
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